

Summary of Safety and Effectiveness

K963676

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**Device Name:** Precision G Blood Glucose Testing System

**Common Name:** Blood Glucose Testing System

**Classification:** "Glucose Test System" - Class II per CFR 862.1345

**Predicate Devices:** Precision QID Blood Glucose Testing System - K944195  
Precision QID Blood Glucose Test Strip - K945887, K962295  
Satellite G Blood Glucose Testing System - K896951

**Description:** The Precision G Blood Glucose Testing System utilizes amperometric biosensor technology to quantitatively measure glucose in whole blood and control solutions. A drop of whole blood or control solution is applied to the target area of the test strip and the assay is automatically initiated. A countdown begins and glucose oxidase catalyzes the oxidation of glucose to produce gluconic acid. During the reaction, electrons are transferred by an electrochemical mediator to the electrode surface, generating a current that is measured by the Precision G Sensor. The size of the current is proportional to the amount of glucose present in the sample, thus giving an accurate reading of glucose concentration after 20 seconds.

The Precision G Blood Glucose Testing System was originally called the Satellite G System (K896951) but was renamed to the Precision G System in 1994.

**Intended Use:** The Precision G Blood Glucose Testing System is intended for in vitro diagnostic use (i.e., for external use only) for the quantitative measurement of glucose in fresh whole blood. The Precision G Blood Glucose Testing System is intended for home or professional use. The product may also be used by healthcare professionals for quantitative measurement of glucose in venous or arterial whole blood, provided the sample is used within 15 minutes.

**Comparison to  
Predicate Device:**

The proposed Precision G Blood Glucose Testing System has technological characteristics equivalent to those of the predicate Satellite G Blood Glucose Testing System (K896951). The proposed Precision G Testing System is also identical in intended use to another predicate device, the Precision QID Testing System (K944195, K945887, K962295). The intended use has been expanded to allow use of the system by home users in addition to use of the system by healthcare professionals.

**Performance  
Studies:**

Performance information on clinical accuracy of the Precision G Blood Glucose Testing System when used by lay users has been compared to clinical accuracy of the Precision G Blood Glucose Testing System when used by trained operators in the table below.

**Accuracy Performance of the Precision G System for Trained Operators and Lay Users versus the YSI.**

	Combined Data Lay User vs. YSI Precision G Lots (170445, 171665)	Combined Data Trained Operator vs. YSI Precision G Lots (170445 and 171665)	Combined Data Trained Operator vs. Lay User Precision G Lots (170445 , 171665)
Correlation Coefficient(s)	0.982	0.984	0.981
Slope	0.966	0.933	1.018
Y-Intercept	13.5 mg/dL	8.7 mg/dL	7.3 mg/dL
Syx	13.9 mg/dL	12.7 mg/dL	14.4 mg/dL
N	200	200	200
Mean Absolute Percent Bias	9.5%	6.5%	10.0%

**Conclusion:** The correlation coefficients and slopes obtained were close to 1.000 and y-intercepts close to 0 mg/dL indicating good correlation of the MediSense Precision G Blood Glucose Testing System to the reference analyzer when testing was conducted by trained operators and lay users. In addition, equivalent results were achieved by Lay Users and Trained Operators using the Precision G Blood Glucose Testing System.